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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,351	02/24/2004	Elizabeth Kornecki	19658Z	8733
7590 12/27/2007				
Peter I. Bernstein				
Scully, Scott, Murphy & Presser, P.C.				
Suite 300				
400 Garden City Plaza				
Garden City, NY 11530				
			EXAMINER	
			WANG, CHANG YU	
			ART UNIT	PAPER NUMBER
			1649	
			MAIL DATE	DELIVERY MODE
			12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,351

Applicant(s)

KORNECKI ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 10/15/07 is acknowledged. Claim 17 is cancelled. Claim 18 is amended. Claims 1-16 and 18-20 are pending in this application. Claims 1-16 and 19-20 are withdrawn with traverse (filed on 2/26/07) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/26/07.
2. Claim 18 is under examination in this office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.
4. Applicant's arguments filed on 10/15/07 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Maintained

In view of the amendment filed on 10/15/07, the following rejections are maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 18 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 and fragments of SEQ ID NO:1, does not reasonably provide enablement for all sequences from other species, mutated sequences, allelic variants, or sequences that hybridize under undefined high stringency conditions to all fragments of SEQ ID NO:1 as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The rejection is maintained for the reasons made of record in the office action mailed 5/15/07, and as follows.

At p.7-8 of the response, Applicant argues that amended claim 18 is enabled for its full scope without undue experimentation because the specification teaches the sequence of SEQ ID NO:1 and it is routine in the art to design and make a specific DNA oligo primer based on SEQ ID NO:1 thereby the specification provides sufficient guidance for a skilled artisan to make and use the DNA oligomers as encompassed by amended claim 18. Applicant's argument has been fully considered but it is not persuasive.

In contrast to Applicant's assertion, the amended claim 18 is not limited to a specific oligo primer derived from SEQ ID NO:1. The limitation recited in amended claim 18 encompasses any DNA molecule or oligomer that can hybridize to any fragment of nucleotides 16-912 or 97-912 of SEQ ID NO:1 because the recitation "a DNA having a nucleotide sequence of nucleotides 16-912 or 97-912 of SEQ ID NO:1 encompasses different length of fragments of 16-912 or 97-912 of SEQ ID NO:1, which include probes

or a polynucleotide with a short sequence that can hybridize to or stick to any DNA sequence of SEQ ID NO:1. Thus, amended claim 18 encompasses polynucleotides that would hybridize under high stringency conditions to a polynucleotide (fragment) of nucleotides 15-912 or 97-912 of SEQ ID NO:1. However, the specification fails to teach how to use other DNA oligomers as recited in instant claim 18.

Due to the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity and the breadth of the claim which fails to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to decipher how to use the claimed invention in its full scope.

Thus, the rejection of claim 18 under 35 U.S.C. §112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is maintained.

6. Claim 18 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons made of record in the office action mailed 5/15/07, and as follows.

At p.8 of the response, Applicant argues that amended claim 18 meets the written description requirement because the specification discloses the sequence of

SEQ ID NO:1 and it is routine in the art to design and make a specific DNA oligo primer based on SEQ ID NO:1. Applicant's argument has been fully considered but it is not persuasive.

In contrast to Applicant's assertion, the amended claim 18 is not limited to a specific oligo primer derived from SEQ ID NO:1. The limitation recited in amended claim 18 encompasses any DNA molecule or oligomer that can hybridize to any fragment of nucleotides 16-912 or 97-912 of SEQ ID NO:1 because the recitation "a DNA having a nucleotide sequence of nucleotides 16-912 or 97-912 of SEQ ID NO:1 encompasses different length of fragments of 16-912 or 97-912 of SEQ ID NO:1 including probes with a short sequence, which can hybridize to any DNA sequence. The specification fails to disclose sufficient species to demonstrate Applicant's possession of such broad genus of DNA oligomer. In addition, the claim fails to define "high stringency conditions", thus, any molecule contains a DNA sequence that can hybridize to any fragments of nucleotides 16-912 or 97-912 of SEQ ID NO:1. However, the specification fails to teach what other DNA molecules or oligomers are but only discloses SEQ ID NO:1. Thus, the specification fails to demonstrate Applicant's possession of such broad genus of DNA oligomers.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is".

and that:

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"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218".

In contrast, the specification provides an invitation for others to discover a representative number of species, or to discover what constitutes any particular portion of the structure that must be conserved, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. Thus, Applicants were not reasonably in possession of the "claimed genus of DNA oligomers", and for the reasons previously made of record. See MPEP 2163.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 stands rejected under 35 U.S.C. 102(b) as being anticipated by GenBank accession number AA101561, October 1996. The rejection is maintained for the reasons made of record in the office action mailed 5/15/07, and as follows.

At p. 9 of the response, Applicant argues that the rejection is moot because amended claim 18 no longer recites SEQ ID NO:2 or its fragments. Applicant's argument has been fully considered but it is not persuasive.

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In contrast to Applicant's assertion, the DNA molecule of the GenBank accession no. AA101561 also read on the DNA oligomer recited in amended claim 18 because SEQ ID NO:2 is 74.5% identical to the whole molecule of SEQ ID NO:1 and with 99.1% local similarity (see sequence alignment below). As previously made of record, GenBank accession number AA101561 discloses a DNA molecule (oligomer) that is 99.2 % identical to SEQ ID NO: 2 over a region of 377 bases. Thus, the DNA fragment (oligomers) of AA101561 also can hybridize to a DNA molecule having a nucleotide sequence of nucleotides 16-912 or 97-912 of SEQ ID NO:1 with high stringency conditions. In addition, the recitation "a DNA having a nucleotide sequence of nucleotides 16-912 or 97-912 of SEQ ID NO:1 encompasses different length of fragments of 16-912 or 97-912 of SEQ ID NO:1 including probes with a short sequence. Thus, any DNA oligomer can hybridize to probes derived from SEQ ID NO:1, which would meet the limitation recited in amended claim 18. Thus, the rejection of Claim 18 under 35 U.S.C. 102(b) for being anticipated by GenBank accession number AA101561 (October 1996) is maintained.

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US-10-785-351-1
; Sequence 1, Application US/10785351
; Publication No. US20040235769A1
; GENERAL INFORMATION:
; APPLICANT: Kornecki, Elizabeth
; APPLICANT: Sobocka, Malgorzata B.
; TITLE OF INVENTION: Human Platelet F11 Receptor
; FILE REFERENCE: 011.00221
; CURRENT APPLICATION NUMBER: US/10/785,351
; CURRENT FILING DATE: 2004-02-24
; PRIOR APPLICATION NUMBER: US/09/397,243
; PRIOR FILING DATE: 1999-09-16
; PRIOR APPLICATION NUMBER: 60/100,638
; PRIOR FILING DATE: 1998-09-16
; NUMBER OF SEQ ID NOS: 27
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 1
; LENGTH: 1822
; TYPE: DNA
; ORGANISM: Homo sapiens
US-10-785-351-1

Query Match          74.5%; Score 537; DB 9; Length 1822;
Best Local Similarity 99.1%; Pred. No. 1.6e-169;
Matches 540; Conservative 0; Mismatches 5; Indels 0; Gaps 0;

Qy          1 AGTGGCCTGATCGCGATGGGGACAAAGGCGCAAGTCGAGAGGAACTGTGTGCTCTTC 60

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Db      1  |||||  AGTGGCCTGATCGCGATGGGGACAAAGGCGCAAGTCGAGAGGAACTGTGTGCTCTTC 60
Qy      61  ATATTGGCGATCCTGTGTGCTCCCTGGCAITGGGCGAGTGTACAGTGCACTCTTCTGAA 120
Db      61  ATATTGGCGATCCTGTGTGCTCCCTGGCAITGGGCGAGTGTACAGTGCACTCTTCTGAA 120
Qy      121  CCTGAAGTCAGAAITCCTGAGAATAATCCTGTGAAGTGTCCGTGCTACTCGGGCTTT 180
Db      121  CCTGAAGTCAGAAITCCTGAGAATAATCCTGTGAAGTGTCCGTGCTACTCGGGCTTT 180
Qy      181  TCTTCTCCCGGTGTGGAGTGAAGTTTGACCAAGGAGACACCAGACTCGTTTGCTAT 240
Db      181  TCTTCTCCCGGTGTGGAGTGAAGTTTGACCAAGGAGACACCAGACTCGTTTGCTAT 240
Qy      241  AATAACAAGATCACAGCTTCCTATGAGGACCGGGTGACCTTCTTGCCAACCTGGTATCACC 300
Db      241  AATAACAAGATCACAGCTTCCTATGAGGACCGGGTGACCTTCTTGCCAACCTGGTATCACC 300
Qy      301  TTCAGTCCGTGACACGGGAAGACACTGGGACATACACTTGTATGGTCTCTGAGGAAGGC 360
Db      301  TTCAGTCCGTGACACGGGAAGACACTGGGACATACACTTGTATGGTCTCTGAGGAAGGC 360
Qy      361  GGCAACAGCTATGGGGAGGTCAAGGTCAAGCTCATCGTGTGTGCTCCATCCAAGCCT 420
Db      361  GGCAACAGCTATGGGGAGGTCAAGGTCAAGCTCATCGTGTGTGCTCCATCCAAGCCT 420
Qy      421  ACAGTTAACATCCCTCCTCTGCAACCATTTGGGAACCGGGCAGTGTGACATGCTCAGAA 480
Db      421  ACAGTTAACATCCCTCCTCTGCAACCATTTGGGAACCGGGCAGTGTGACATGCTCAGAA 480
Qy      481  CAAGATGGTTCCCAACCTTCTGAATACACCTGGTTCAAAGATGGGATAGTGACGCTATA 540
Db      481  CAAGATGGTTCCCAACCTTCTGAATACACCTGGTTCAAAGATGGGATAGTGATGCCTACG 540
Qy      541  ATCCC 545
Db      541  AATCC 545

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 18 stands rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 6699688 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The rejection is maintained for the reasons made of record in the office action mailed 5/15/07, and as follows.

At p. 9 of the response, Applicant argues that US 6699688 is not directed to a DNA oligomer so the extending right to exclude does not apply to claim 18. Applicant's argument has been fully considered but it is not persuasive.

In contrast to Applicant's assertion, US6699688 also claims a DNA oligomer because an isolated DNA molecule comprising a nucleic acid sequence having 16-912 nucleotides of SEQ ID NO:1 is a DNA oligomer. Thus, the rejection claims under the ground of nonstatutory double patenting over claim 1 of US Patent No. 6699688 is maintained of record until a terminal disclaimer is filed. It is noted that traversal at the time of indication of allowable subject matter will not be considered timely.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on 10/15/07.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because the claims recite "under high stringency conditions". Applicant describes an example of high stringency condition on p. 16-17 of the specification but fails to define/describe what is encompassed within "high stringency conditions". The disclosure fails to set forth the metes and bounds of what is encompassed within the definition of such high stringency conditions. There are numerous conditions that fall in this definition, therefore the meets and bounds of what is intended by the claim cannot be ascertained. Thus, the claim is indefinite.

Conclusion

10. NO CLAIM IS ALLOWED.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/

Chang-Yu Wang, Ph.D.
December 3, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER

